247 CMR 7:00: WHOLESALE DRUGGISTS

Section

7.01: Scope and Purpose

The purpose of 247 CMR 7.00 is to implement the Federal Prescription Drug Marketing Act of 1987 ("PDMA"), U.S. Public Law 100-293, codified at 21 U.S.C. §§ 321 *et seq*. The PDMA requires that all entities engaged in the interstate and/or intrastate wholesale distribution of prescription drugs be licensed in each state where they are engaged in such activity.

247 CMR 7.00 applies to every wholesale distributor located in the Commonwealth of Massachusetts who engages in the sale, distribution, or delivery at wholesale of prescription drugs.

The purpose of 247 CMR 7.00 is to provide minimum standards, terms and conditions for the licensing by the Board of Registration in Pharmacy of persons located in Massachusetts who engage in the sale, distribution, or delivery at wholesale of prescription drugs.

7.02: Licensing Requirements

(1) Every wholesale distributor located in the Commonwealth of Massachusetts who engages in wholesale distribution of prescription drugs shall be licensed by the Board in accordance with the laws and regulations of the Commonwealth before engaging in such wholesale distribution.

(2) Applications for a license to conduct a wholesale drug business in the Commonwealth shall be made upon application forms furnished by the Board. Each application shall be completely filled out and signed by each applicant under oath before a notary public. The Board shall not consider any applications within 15 days after the date of its filing with the Board. The Board shall not consider any application which has been improperly completed or which is not accompanied by the appropriate fee(s).

(3) The Board may require a hearing upon the merits of any application for a license to conduct a wholesale drug business. Where such a hearing is required, the Board shall give the applicant seven days notice by certified mail, of the date, time, and place of the hearing.

(4) Any person who is engaged in the wholesale drug business at more than one location shall obtain a license for each location.

(5) Minimum Required Information for Licensure. The Board requires the following information from each wholesale drug distributor as part of the initial licensing procedure and as part of any renewal of such license:

(a) The name, full business address, and telephone number of the applicant or licensee;

(b) all trade or business names used by the applicant or licensee;

(c) addresses, telephone numbers, and the names of contact persons for each facility used by the applicant or licensee for the storage, handling, and distribution of prescription drugs;

(d) the type of ownership or operation (*i.e.*, partnership, corporation, or sole proprietorship); and

1. if a person, the name of the person;
2. if a partnership, the name of each partner, and the name of the partnership;
3. if a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation, and the name of the parent company, if any;
4. if a sole proprietorship, the full name of the sole proprietor and the name of the business entity;
5. an indication as to whether the applicant or licensee will distribute controlled substances, legend drugs, and/or over-the-counter drugs, as well as a statement concerning the types of drugs to be distributed.

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(6) Changes in any information in 247 CMR 7.02(5) shall be submitted to the Board in writing within 30 days after such change.

(7) Minimum Qualifications. The Board shall consider the following factors at a minimum in issuing, renewing, or revoking a license to engage in the wholesale distribution of prescription drugs:

(a) Any convictions of the applicant or licensee under any federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

(b) any felony convictions of the applicant or licensee under federal, state, or local laws;

(c) the past experience of the applicant or licensee in the manufacture or distribution of prescription drugs, including controlled substances;

(d) the furnishing by the applicant or licensee of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

(e) suspension, revocation, or other sanction(s) by federal, state, or local government of any license or registration currently or previously held by the applicant or licensee for the manufacture or distribution of any drugs, including controlled substances;

(f) compliance with licensing or registration requirements under previously granted licenses or registrations, if any;

(g) compliance with the requirements to maintain and/or make available to state licensing authorities or to federal, state, or local law enforcement officials those records required to be maintained by wholesale drug distributors;

(h) failure to provide adequate control over the distribution, diversion, theft, and/or loss of drugs;

(i) compliance with all requirements set forth in 247 CMR 7.00; and

(j) any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

(8) The Board reserves the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest.

(9) Personnel. As a condition for receiving and retaining a wholesale drug distributor license, the licensee shall require each person employed in any prescription drug wholesale distribution activity to have education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such a manner as to provide assurance that the drug product quality, safety, and security will at all times be maintained as required by law.

7.03: Penalties

(1) The agents of the Board may inspect and investigate all wholesale drug distributors of drugs and medicines and shall report all violations of Board regulations and statutes to the Board. Board agents shall provide to the licensee a copy of the inspection report within 15 days of such inspection. At the direction of the Board, Board agents may apply for criminal complaints to be issued against persons guilty of any such violations.

(2) Every person who is licensed to conduct a wholesale drug business shall not sell or deliver drugs to any unauthorized person, whether upon prescription, at retail, or otherwise.

(3) Except under the direct supervision of a registered pharmacist, and in compliance with federal Current Good Manufacturing Practices (CGMP's), a person who is licensed to conduct a wholesale drug business shall not package or repackage any drug for resale, nor shall said person label or relabel any drug container.

(4) The Board may, after hearing or by agreement, suspend or revoke any licenses granted under 247 CMR 7.00 for any violation of federal, state or local drug laws or regulations or for any violation of Board laws or regulations governing the wholesale drug business.

7.04: Minimum Requirements for the Storage and Handling of Prescription Drugs and for the Establishment and Maintenance of Prescription Drug Distribution Records

The following shall constitute minimum requirements for the storage and handling of prescription drugs, and for the establishment and maintenance of prescription drug distribution records by wholesale drug distributors and their officers, agents, representatives, and employees:

(1) Facilities. All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(a) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(b) have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(c) have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened;

(d) be maintained in a clean and orderly condition; and

(e) be free from infestation by insects, rodents, birds, or vermin of any kind.

(2) Security. All facilities used for wholesale drug distribution shall be secure from unauthorized entry in accordance with the requirements of the Board and federal regulations. The following guidelines shall be observed:

(a) Access from outside the premises shall be kept to a minimum and be well-controlled.

(b) The outside perimeter of the premises shall be well-lighted.

(c) Entry into areas where prescription drugs are held shall be limited to authorized personnel.

(d) All facilities shall be equipped with an alarm system to detect entry after hours.

(e) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(f) All facilities shall conduct a thorough background check for each employee.

(g) All facilities shall report a theft or loss of a significant amount of controlled substances by submitting to the Board a copy of "Report or Loss of Controlled Substances" (DEA BND Form 106) within seven days of such theft or significant loss, and where applicable, shall comply with the reporting requirements of the DEA, the Department, and the state and local police.

(3) Storage.

(a) All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium such as the United States Pharmacopoeia/National Formulary (USP/NF).

(b) If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(c) appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs.

(d) The record-keeping requirements in 247 CMR 7.04(6) shall be followed for all stored drugs.

(4) Examination of Materials.

(a) Upon receipt, each outside shipping container shall be visually examined for identity to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(b) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(c) The record keeping requirements in 247 CMR 7.04(6) shall be followed for all incoming and outgoing prescription drugs.

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(5) Returned, Damaged, and Outdated Prescription Drugs.

(a) Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed in accordance with all applicable state and federal regulations or returned to the supplier.

(b) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other prescription drugs until they are either destroyed in accordance with all applicable state and federal regulations or returned to the supplier.

(c) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed in accordance with all applicable state and federal regulations, or returned to the supplier, unless examination, testing or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(d) The record-keeping requirements in 247 CMR 7.04(6) shall be followed for all out-dated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

(6) Record Keeping.

(a) Wholesale drug distributors shall establish and maintain, in a manner consistent with good business practices, complete and accurate inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information:

1. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped, or in the case of distribution, the name and address of the purchaser;
2. the identity and quantity of the drugs received and distributed or disposed of; and
3. the dates of receipt and distribution or other disposition of the drugs. In the case of registered wholesale drug distributors who are also licensed by the Board as pharmacies, no records shall be required to be maintained for the receipt or disposition of over-the-counter drugs.

(b) Inventories and records shall be made available for inspection and photocopying by any authorized official of any governmental entity charged with enforcement of 247 CMR 7.00 for a period of two years following disposition of the drugs.

(c) Records described in 247 CMR 7.04(6) that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the two-year retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized official of any governmental agency charged with enforcement of 247 CMR 7.00.

(7) Written Policies and Procedures. Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures the following:

(a) A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement if such deviation is temporary and appropriate.

(b) A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

1. Any action initiated at the request of the United States Food and Drug Administration or other federal, state, or local law enforcement or other government agency, including the Board;

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2. any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

3. any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(c) A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(d) A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for two years after disposition of the outdated drugs.

(e) In the case of wholesale drug distributors who are also licensed by the Board as pharmacies, the requirements of 247 CMR 7.05 shall apply to legend drugs only.

(8) Responsible Persons. Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(9) Compliance with Federal, State, and Local Laws.

(a) Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations.

(b) Wholesale drug distributors shall permit the agents of the Board and authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

(c) Wholesale drug distributors that deal in controlled substances as defined in M.G.L. c. 94C shall register with the Board, the Massachusetts Department of Public Health and with the United States Drug Enforcement Administration (DEA), and shall comply with all applicable state, local and federal regulations.

(d) Wholesale drug distributors shall be subject to the provisions of any applicable federal, state, and local laws that relate to prescription drug product salvaging or reprocessing.

REGULATORY AUTHORITY

247 CMR 7.00: M.G.L. c. 112, §. 36A, 36B, 36C and 42A; c. 94C, § 6.

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